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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/753,116	01/07/2004	Michael J. Kubek	225849	5202

23460 7590 09/10/2007

LEYDIG VOIT & MAYER, LTD
TWO PRUDENTIAL PLAZA, SUITE 4900
180 NORTH STETSON AVENUE
CHICAGO, IL 60601-6731

EXAMINER	
AZPURU, CARLOS A	
ART UNIT	**PAPER NUMBER**
1615	

MAIL DATE	DELIVERY MODE
09/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/753,116	KUBEK, MICHAEL J.	
	Examiner	Art Unit	
	Carlos A. Azpuru	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 June 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the amendment filed 06/18/2007.

The rejection under 36 USC 112, first paragraph is withdrawn in view of applicant's amendment.

The following rejection is cited in view of an updated search:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,360,610 (Tice et al) in view of EP 0 256 726 (EP'726).

Tice et al discloses a method of implanting microspheres directly into the central nervous system (see Abstract). The bioactive agents included are neurotransmitters, neuropeptides and neurotrophic factors (see col. 4, lines 44-50). Polymers used in the implanted microspheres are listed at claims 1, and 9-11. It should be noted that these are biodegradable. Tice et al further disclose a microsphere content of 10 to 80 % of bioactive (see claim 7). This clearly overlaps with the percentage set out in the claims of

the instant claims. Microparticulate implanted drug delivery systems are art recognized for their local delivery and are used for their local drug delivery properties. Therefore, the property of having a "size and shape sufficient to prevent dispersion of the microstructure from the central nervous system locus is art recognized (see discussion of microspheres at col 3, lines 10-67). Implantation is in the central nervous system (see col. 4, lines 1-15). The use of cannulas to deliver bioactive to the central nervous system is well recognized as shown at col. 1, lines 50-53. Tice et al differs from the instantly claimed invention in that TRH is not specifically disclosed for implantation into the central nervous system.

EP'726 discloses microencapsulated TRH (see Abstract and claims). EP'726 also uses some of the same polymers to construct their microencapsulated formulations (see claims 9-12). EP'726 further teaches a content of about 5 – 80% TRH at page 4, lines 28-30. This is commensurate with the amounts envisioned by Tice et al. Selection of a central locus is taught by the Tice reference, as well as implantation to such a central nervous site using the same biodegradable microstructures, while the specific TRH microstructures are taught by EP'726. EP'726 further recognizes that shape of the implant is a function of several well known variables (See page 4, lines 39-52). Applicant has not shown any criticality in the use of non-spherical microstructures, and further, seems to support an equivalence in using any number of shapes in the specification at page 3, lines 15-21. As such, those of ordinary skill in the art would found it well within their skill to use the method of implanting biodegradable microparticles disclosed by Tice et al, and further to more specifically use

microencapsulated TRH of EP'726 as one of the CNS implants of non-spherical shape with a reasonable expectation of beneficial results. While the references do not specifically recite the up regulation of glutamate and/or aspartate, they teach the implantation method using the instantly claimed microstructures. Since the same method of implanting the same microstructures of TRH is suggested by the combination of these references, one would expect similar physiological effects as a result. As such, those of ordinary skill would expect similar increases in the release of glutamate and/or aspartate as a result of the prolonged release of TRH from these microstructures within the central nervous system. There are no unusual and/or unexpected results which would rebut prima facie obviousness. The instant method of increasing glutamate and/or aspartate release in the central nervous system would have therefore been obvious to one of ordinary skill at the time of invention given the teachings of Tice et al in view of EP'726.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Carlos A. Azpuru
Primary Examiner
Art Unit 1615

caz